PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P030497WO/CJM	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/01882	International filing date *(day/month/year)* 02.05.2003	Priority date *(day/month/year)* 02.05.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/315		
Applicant CHIRON S.R.L., et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.10.2003	18.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Mossier, B Telephone No. +49 89 2399-8706

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01882

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-143 as originally filed

Claims, Numbers

1-28 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01882

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1- 21, 23-28 (all partially) and 22 (complete)

because:

☒ the said international application, or the said claims Nos. 17 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1- 21, 23-28 (all partially) and 22 (complete)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-21, 23-28
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-21, 23-28
Industrial applicability (IA)	Yes:	Claims	1-16, 18-21, 23-28
	No:	Claims	

2. Citations and explanations

see separate sheet

Present application provides 686 proteins from group B streptococcus (*Streptococcus agalactiae*) and group A streptococcus (*Streptococcus pyogenes*). The amino acid sequences and the corresponding nucleic sequences are claimed; no experimental data disclosing specific functions are shown.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 Claim 17 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
For the assessment of the present claim 17 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

III.2 The International Preliminary Examining Authority (IPEA) agrees with the objection put forward by the International Searching Authority (ISA) as to lack of unity (see ISA/210 annex).

As the applicant has not had a search report drawn up on the other inventions, only Invention 1, claims 1-21, 23-28 (all partially), respectively a protein as depicted in SEQ ID NO:2 and which is encoded by the nucleic acid molecule as depicted in SEQ ID NO:1 (remark: said sequences are derived from *Streptococcus agalactiae*), will be subjected to International Preliminary Examination in accordance with Article 34(3)(c) PCT.

III.3 Claim 22 relates to subject matter for which no search is required according to Rule 39.1(v) PCT (see ISA/210).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 The following documents were taken into account:

D1: WO 99 42588 A (BIOCHEM VACCINS INC ;BRODEUR BERNARD R (CA); CHARLEBOIS ISABELLE () 26 August 1999 (1999-08-26)

The International Preliminary Examination Report has been based on an assumed valid priority for the present application. Should the priority of the present application not be valid, the P,X document cited in the Search Report would be relevant with respect to novelty and inventive step (Article 33(2) and 33(3) PCT).

V.2 D1 discloses *Streptococcus agalactiae* (Group B streptococcus; GBS) proteins and polynucleotides encoding said proteins. Clone 7, as depicted in SEQ ID NO:37 (nucleotide sequence) and in SEQ ID NO:38 (amino acid sequence), shows 100%identity in an 283 aa overlap to SEQ ID NO:2 (24-306:1-283), respectively 99,9%identity in a 849 nt overlap to SEQ ID NO:1 (70-918:1-849). D1 further refers to hetero and homo polypeptide multimers, to nucleic acid molecules which hybridize to the claimed polynucleotide as well as to vaccine compositions comprising one or more GBS polypeptides and to diagnostic methods for detecting streptococcus organism in a biological sample (page 8, lines 21 - 33; page 12, lines 16 - 34; page 9, lines 20 - 23; page 15, line 5 - page 17, line 21) Hence, D1 anticipates the subject matter referred to in claims 1 - 21, and 23 - 28. and therefore said claims appear to lack novelty under Article 33(2) PCT.